Bayer HealthCare
Diabetes Care

NOV 2 1 2006

510(k) SUMMARY

Ascensia® BREEZE®2 Blood Glucose Monitoring System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is k062347

Prepared:	August 9, 2006
Submitter:	Bayer HealthCare, Diabetes Care
Address:	Bayer HealthCare, Diabetes Care 430 South Beiger Street Mishawaka, IN 46544 Phone (574) 256-7719; FAX (574) 256-3519
Contact:	Marc A. Henn, Regulatory Affairs Specialist
Device:	Trade/Proprietary Name: Ascensia® BREEZE®2 Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Meter
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75 CGA, (Glucose Oxidase, Glucose)
Predicate Device:	Ascensia® BREEZE® Diabetes Care System, K024062
Device Description:	The Ascensia® BREEZE®2 Blood Glucose Monitoring System consists of: 1. Ascensia® BREEZE®2 Blood Glucose Monitor 2. Ascensia® BREEZE®2 Blood Glucose Test Strips 3. Ascensia® BREEZE®2 Control Solution

Intended Use:	The Ascensia® BREEZE®2 Blood Glucose Monitoring System consisting of the Ascensia® BREEZE®2 Blood Glucose Meter, Ascensia® BREEZE®2 Reagent Strips and Ascensia® BREEZE®2 Control Solution is for the measurement of glucose in whole blood. The Ascensia® BREEZE®2 Blood Glucose Monitoring System allows the user an option to use the palm and forearm in addition to the fingertip (testing) to collect capillary blood for self-monitoring of blood glucose within certain conditions as explained in the labeling. Ascensia® BREEZE®2 Blood Glucose Monitoring System is an over-the-counter (OTC) device used by persons with diabetes. Ascensia® Breeze®2 Blood Glucose Monitoring System is not for use with neonatal blood specimens. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.
Technological Characteristics:	The Ascensia® BREEZE®2 Blood Glucose Monitoring System employs an amperometric glucose oxidase method to measure glucose in blood. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. Blood glucose results are referenced to plasma glucose. The system has a linearity response to glucose from 20-600 mg/dL.
Assessment of Performance:	A validation of the Ascensia® BREEZE®2 Blood Glucose Monitoring System was performed in a clinical setting by persons with diabetes. The subject meter results for capillary blood samples were compared with BREEZE®2 results obtained by a healthcare professional and results of a laboratory glucose analyzer. The studies showed improved performance compared with past clinical studies of the original Ascensia® BREEZE® Blood Glucose Monitoring System.
Conclusion:	The results of the clinical evaluations of The Ascensia® BREEZE®2 Blood Glucose Monitoring System demonstrated that the device can produce blood glucose results that are substantially equivalent to results obtained on the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Roger Sonnenburg
Manager, Regulatory Affairs
Bayer HealthCare, LLC
430 South Beiger St.
Mishawaka, IN 46544

NOV 2 1 2006

Re: k062347
Trade/Device Name: Ascensia® BREEZE®2 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: November 15, 2006
Received: November 16, 2006

Dear Mr. Sonnenburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k062347

Device Name: Ascensia® BREEZE®2 Blood Glucose Monitoring System

Indications For Use: The Ascensia® BREEZE®2 Blood Glucose Monitoring System consisting of the Ascensia® BREEZE®2 Blood Glucose Meter, Ascensia® BREEZE®2 Reagent Strips and Ascensia® BREEZE®2 Control Solution is for the measurement of glucose in whole blood. The Ascensia® BREEZE®2 Blood Glucose Monitoring System allows the user an option to use the palm and forearm in addition to the fingertip (testing) to collect capillary blood for self-monitoring of blood glucose within certain conditions as explained in the labeling. Ascensia® BREEZE®2 Blood Glucose Monitoring System is an over-the-counter (OTC) device used by persons with diabetes. Ascensia® BREEZE®2 Blood Glucose Monitoring System is not for use with neonatal blood specimens. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K062347